

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
 (Chapter II of the Patent Cooperation Treaty)  
 (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 504320 NJC	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. PCT/NZ2004/000165	International filing date (day/month/year) 27 July 2004	Priority date (day/month/year) 30 July 2003
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>7</sup> A61M 16/00		
Applicant FISHER & PAYKEL HEALTHCARE LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:
    - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 25 May 2005	Date of completion of the report 4 November 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustrelia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  AMOD PRADHAN Telephone No. (02) 6283 2510

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/NZ2004/000165

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1 - 12 as originally filed/furnished

pages\* received by this Authority on with the letter of

pages\* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished

pages\* as amended (together with any statement) under Article 19

pages\* 13 - 14 received by this Authority on 25 May 2005 with the letter of 25 May 2005

pages\* received by this Authority on with the letter of

☒ the drawings:

pages 1 - 10 as originally filed/furnished

pages\* received by this Authority on with the letter of

pages\* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (specify):

☐ any table(s) related to the sequence listing (specify):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (specify):

☐ any table(s) related to the sequence listing (specify):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/NZ2004/000165

## Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

☐ complied with.☒ not complied with for the following reasons:

1. Claims 1-3 are directed to a forehead rest for a respiratory mask including a deformable resilient member comprising a deformable resilient member having a top surface and a base connected by two side walls, said side walls being substantially thinner in width than said top surface, said walls in use are compressible. It is considered that said side walls being substantially thinner in width than said top surface, said side walls in use are compressible comprises a first "special technical feature".
2. Claim 4 is directed to a forehead rest for a respiratory mask including a deformable resilient member comprising a hollow conical shape where in use and under compression the top part of said hollow cone deforms or the side walls of said cone deform. It is considered that the hollow conical shape of said deformable resilient member where in use and under compression the top part of said hollow cone deforms or the side walls of said cone deform comprises a second "special technical feature".
3. Claims 5-8 are directed to a forehead rest for a respiratory mask including a user-adjustable deformable resilient member configured to in use rest against the face of a patient. It is considered that the user-adjustable deformable resilient member comprises a third "special technical feature".

It is noted that claim 9 is defined by the accompanying figures of the specification and, as such, unity of invention exists between claim 9 and each group of claims for which the figures relate to.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/NZ2004/000165Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1 - 9	YES
	Claims	NO
Inventive step (IS)	Claims 1 - 9	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 - 9	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

Novelty (N) Claims 1-9

## Claims 1-3

Amended claims 1-3 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose a forehead rest including a deformable resilient member, said deformable resilient member having a top surface and a base connected by two side walls, said side walls being substantially thinner in width than said top surface, said side walls in use are compressible.

## Claim 4

Amended claim 4 meets the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose a forehead rest including a deformable resilient member being of a hollow conical shape where in use and under compression the top part of said hollow cone deforms or the side walls of said cone deform.

## Claims 5-8

Amended claims 5-8 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose a forehead rest including a user-adjustable deformable resilient member.

See however the indication contained in Box VI "Certain documents cited".

It is noted that since claim 9 is defined by the accompanying figures of the specification, claim 9 may be considered as part of each group of claims for which the figures relate to.

Inventive Step (IS) Claims 1-9

## Claims 1-3

Amended claims 1-3 meet the criteria set out in PCT Article 33(3) with regard to the requirement of Inventive Step because the prior art does not obviously suggest to a person skilled in the art a forehead rest including a deformable resilient member, said deformable resilient member having a top surface and a base connected by two side walls, said side walls being substantially thinner in width than said top surface, said walls in use are compressible.

## Claim 4

Amended claim 4 meets the criteria set out in PCT Article 33(3) with regard to the requirement of Inventive Step because the prior art does not obviously suggest to a person skilled in the art a forehead rest including a deformable resilient member being of a hollow conical shape where in use and under compression the top part of said hollow cone deforms or the side walls of said cone deform.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
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## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
P, X WO 2004/022145	18 March 2004	5 September 2003	6 September 2002

This document explicitly discloses all of the features of claims 5 and 7. See in particular page 20, lines 7-23 and Figs. 63-66.

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day/month/year)Date of written disclosure  
referring to non-written disclosure  
(day/month/year)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/NZ2004/000165

## Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 7 is not clear because a claim cannot be appended to itself, but appears it should be appended to claim 5 instead.

Claims 6 and 8 are not clear because they are appended to claim 7, but appears they should be appended to claim 5 instead.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/NZ2004/000165

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V

## Claims 5-8

Amended claims 5-8 meet the criteria set out in PCT Article 33(3) with regard to the requirement of Inventive Step because the prior art does not obviously suggest to a person skilled in the art a forehead rest including a user-adjustable deformable resilient member.

See however the indication contained in Box VI "Certain documents cited".

It is noted that since claim 9 is defined by the accompanying figures of the specification, claim 9 may be considered as part of each group of claims for which the figures relate to.

Industrial Applicability (IA) Claims 1-9

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

P Category Documents

With regard to the document(s) listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/NZ2004/000165

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> Int. Cl. <sup>7</sup> : A61M 16/00 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI IPC A61M, A62B and keywords (mask, rest, cushion, pad, support, mount, forehead, brow) and similar terms		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6119693 A (KWOK et al) 19 September 2000 Whole document	1, 2
X	EP 1205205 A2 (GOTTLIEB WEINMANN GERATE FUR MEDIZIN UND ARBEITSSCHUTZ GMBH & CO) 15 May 2002 Whole document	1, 2
X	DE 10045183 A1 (MAP MEDIZINTECHNIK FUR ARZT UND PATIENT GMBH & CO KG) 16 May 2002 Whole document	1
X	US 2003/0066531 A1 (GRADON et al) 10 April 2003 Whole document	1-4
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
Date of the actual completion of the international search 26 August 2004		Date of mailing of the international search report - 3 SEP 2004
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer SUE THOMAS Telephone No : (02) 6283 2454



# INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ2004/000165

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	US 2004/0045551 A1 (EATON et al) 11 March 2004 Whole document	1
P, X	WO 2004/022145 A1 (RESMED LIMITED) 18 March 2004 Page 20, lines 7-23 Figs. 63-66	1, 7, 9.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ2004/000165

### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/NZ2004/000165

### Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

#### Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 5 are directed to a forehead rest for a respiratory mask including a deformable resilient member comprising a top surface and a base connected by two side walls, said top surface being substantially thicker than said side walls. It is considered that said top surface being substantially thicker than said side walls comprises a first "special technical feature".
2. Claim 6 is directed to a forehead rest for a respiratory mask including a deformable resilient member comprising a hollow conical shape. It is considered that the hollow conical shape of said deformable resilient member comprises a second "special technical feature".
3. Claims 7 to 10 are directed to a forehead rest for a respiratory mask including a user-adjustable deformable resilient member configured to in use rest against the face of a patient. It is considered that the adjustability of the deformable resilient member comprises a third "special technical feature".

It is noted that claim 11 is defined by the accompanying figures of the specification and, as such, unity of invention exists between claim 11 and each group of claims.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/NZ2004/000165

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	6119693	US	6463931	US	2002148473	US	2003005935
		US	2004060561				
EP	1205205	DE	10155152				
DE	10045183						
US	2003066531	AU	51876/01	AU	51877/01	AU	67947/01
		CA	2350351	CA	2350356	CA	2370995
		CA	2407118	CA	2413938	CA	2457277
		EP	1163923	EP	1163924	EP	1289590
		EP	1302212	EP	1306098	EP	1425060
		JP	2002028240	JP	2002095751	NZ	508219
		NZ	514972	US	2002005201	US	2002014241
		US	2003000533	US	2003062048	US	2003089373
		US	2003111080	US	2003154978	US	2003196659
		US	2003217746	US	2004035428	US	2004065327
		WO	0195965	WO	03022341	WO	03030978
US	2004045551	WO	2004021960				
WO	2004022145	EP	1334742	JP	2003175106	US	2003075180
		US	2004112384	US	2004112385	US	2004112387
		US	2004118406	WO	2004022144	WO	2004022146
		WO	2004022147				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX